REMARKS

Claims 1, 3-7 and 9-11 are pending and under consideration. Claim 1 has been amended to recite an active step where the fibroblast sample is contacted with the disease-specific IgG from the same patient. Claim 1 has further been amended to more specifically point out that detecting binding of the disease-specific antibodies to the IGF-1R autoantigen is a requirement of the claimed method. Claims 9-11 have been cancelled herein without prejudice to pursuing the cancelled subject matter in a future application claiming priority to the instant application. The amendments do not add any new matter and entry is respectfully requested.

Regarding Obviousness-Type Double Patenting

The rejection of claims 1, 3, 6-7 and 9-11 on the ground of non-statutory obviousness-type double patenting over claims 1-4 of U.S. Patent No. 6,936,426 is respectfully traversed. This rejection has been rendered moot with regard to claims 9-11, which have been cancelled herein without prejudice. Claim 1 has been amended to clarify that the claimed methods require detection of binding of the disease-specific antibodies to the IGF-1R autoantigen. Patent No. 6,936,426 neither teaches nor suggests even the identity of the autoantigen responsible for the autoimmune response in Graves Disease. Removal of the rejection of claims 1, 3, 6-7 and 9-11 on the ground of non-statutory obviousness-type double patenting over claims 1-4 of U.S. Patent No. 6,936,426 is respectfully requested.

Regarding 35 U.S.C. § 112, First Paragraph (Enablement)

Applicants respectfully traverse the rejection of claims 1, 3, 6-7 and 9-11 under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. This rejection has been rendered moot with regard to claims 9-11, which have been cancelled herein without prejudice.

While Applicant respectfully maintain that the specification enables the full scope of the claimed invention, base claim 1 has been amended to recite the embodiments indicated in the Office Action to be enabled, rendering moot the rejection. Accordingly, Applicants respectfully request removal of the rejection of claims 1 and 3 and 6-7 under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

Regarding 35 U.S.C. § 102

Unless a reference discloses not only all of the limitations claimed, but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102. Net MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1371 (Fed. Cir. 2008). The concept of "inherent disclosure" does not alter the requirement that all elements must be disclosed in an anticipatory reference in the same way as they are arranged or combined in the claim. Transclean Corp. v. Bridgewood Servs., Inc., 290 F.3d 1364, 1373 (Fed. Cir. 2002).

Sciaky et al.

Applicants respectfully traverse the rejection of claims 1, 3, 6-7and 9-11 under 35 U.S.C. § 102(a) as allegedly being anticipated by Sciaky et al., *The Journal of Immunology* 164: 3806-3814 (2000). This rejection has been rendered moot with regard to claims 9-11, which have been cancelled herein without prejudice.

Claim 1 has been amended to clarify that the claimed methods require detection of binding of the disease-specific antibodies to the IGF-1R autoantigen. Sciaky et al. do not disclose the identity of the autoantigen responsible for the autoimmune response in Graves Disease. More importantly, Sciaky et al. do not disclose, expressly or inherently, the detection of binding of the disease-specific antibodies to the IGF-1R autoantigen. Accordingly, Applicants respectfully request removal of the rejection of claims 1, 3, 6-7and 9-11 under 35 U.S.C. § 102(a) allegedly being anticipated by Sciaky et al., *The Journal of Immunology* 164: 3806-3814 (2000).

Blaschke et al.

Applicants respectfully traverse the rejection of claims 1, 3, 7 and 9 under 35 U.S.C. 102(b) as being anticipated by Blaschke et al., *J. Invest. Dermatol.* 113:658-663 (1999). This rejection has been rendered moot with regard to claim 9, which has been cancelled herein without prejudice.

Claim 1 has been amended to clarify that the claimed methods require detection of binding of the disease-specific antibodies to the IGF-1R autoantigen. Blaschke et al. does not disclose the identity of the autoantigen responsible for the autoimmune response in Graves Disease. More importantly, Blaschke et al. do not disclose, expressly or inherently, the detection of binding of the disease-specific antibodies to the IGF-1R autoantigen. Accordingly, Applicants

respectfully request removal of the rejection of claims 1, 3, 7and 9 under 35 U.S.C. § 102(b) allegedly being anticipated by Blaschke et al., *J. Invest. Dermatol.* 113:658-663 (1999).

Schroder et al.

Applicants respectfully traverse the rejection of claims 1, 3, 7 and 10 under 35 U.S.C. 102(b) as being anticipated by Schroder et al., *J. Leukoc. Biol.*, 59:1-5 (1996). This rejection has been rendered moot with regard to claim 10, which has been cancelled herein without prejudice.

Claim 1 has been amended to clarify that the claimed methods require detection of binding of the disease-specific antibodies to the IGF-1R autoantigen. Schroder et al. does not disclose the identity of the autoantigen responsible for the autoimmune response in Graves Disease. More importantly, Schroder et al. do not disclose, expressly or inherently, the detection of binding of the disease-specific antibodies to the IGF-1R autoantigen. Accordingly, Applicants respectfully request removal of the rejection of claims 1, 3, 7and 10 under 35 U.S.C. § 102(b) allegedly being anticipated by Schroder et al., *J. Leukoc. Biol.*, 59:1-5 (1996).

Fukuoka et al.

Applicants respectfully traverse the rejection of claims 1, 3, 7 and 10 under 35 U.S.C. 102(b) as being anticipated by Fukuoka et al., *Brit. J. Pharm.* 124:1433-1438 (1998) . This rejection has been rendered moot with regard to claims 9-11, which have been cancelled herein without prejudice.

Claim 1 has been amended to clarify that the claimed methods require detection of binding of the disease-specific antibodies to the IGF-1R autoantigen. Fukuoka et al. does not disclose the identity of the autoantigen responsible for the autoimmune response in Graves Disease. More importantly, Fukuoka et al. do not disclose, expressly or inherently, the detection of binding of the disease-specific antibodies to the IGF-1R autoantigen. Accordingly, Applicants respectfully request removal of the rejection of claims 1, 3, 7and 10 under 35 U.S.C. §102(b) allegedly being anticipated by Fukuoka et al., *Brit. J. Pharm.* 124:1433-1438 (1998)

Noso et al.

Applicants respectfully traverse the rejection of claims 1, 3, 7 and 10 under 35 U.S.C. §102(b) as being anticipated by Noso et al., *J. Immunol.* 156:1946-1953 (1996). This rejection has been rendered moot with regard to claim 10, which has been cancelled herein without prejudice.

Claim 1 has been amended to clarify that the claimed methods require detection of binding of the disease-specific antibodies to the IGF-1R autoantigen. Noso et al. does not disclose the identity of the autoantigen responsible for the autoimmune response in Graves Disease. More importantly, Noso et al. do not disclose, expressly or inherently, the detection of binding of the disease-specific antibodies to the IGF-1R autoantigen. Accordingly, Applicants respectfully request removal of the rejection of claims 1, 3, 7and 10 under 35 U.S.C. § 102(b) allegedly being anticipated by Noso et al., *J. Immunol.* 156:1946-1953 (1996).

Regarding 35 U.S.C. § 103

Applicants respectfully traverse the rejection of claims 1 and 6 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Schroder et al, *supra*, Fukuoka et al, *supra*, and Noso et al, *supra*, all in view of U.S. Patent No. 5,766,866.

The deficiencies of Schroder et al, *supra*, Fukuoka et al, *supra*, and Noso et al, supra, are set forth above in addressing the novelty rejections. Combining these references and viewing them in the context of U.S. Patent No. 5,766,866, does not cure the deficiencies discussed above of each of the primary references. A combination of the prior art, even if supported by a motivation to combine, must teach or suggest all the limitations of the claims. *CFMT, Inc. v. YieldUp Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) *See In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983); *In re Royka*, 490 F.2d 981, 985 (CCPA 1974) HN15(obviousness requires a suggestion of all limitations in a claim). The cited references, whether viewed alone or in combination, fail to teach or suggest the identity of the autoantigen responsible for the autoimmune response in Graves Disease. More importantly, the cited references, whether viewed alone or in combination, fail to teach or suggest the detection of binding of the disease-specific antibodies to the IGF-1R autoantigen. Accrdingly, Applicants respectfully request removal of the rejection of claims 1 and 6 under 35 U.S.C. § 103(a) as allegedly rendered obvious over Schroder et al, *supra*, Fukuoka et al, *supra*, and Noso et al, *supra*, all in view of U.S. Patent No. 5,766,866.

CONCLUSION

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to call the undersigned attorney if there are any questions.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP

/Astrid R. Spain/

Astrid R. Spain
Registration No. 47,956

11682 El Camino Real, Suite 400
San Diego, CA 92130-2047
Phone: 858.720.3300 ARS:cjh:llf
Facsimile: 858.720.7800
Date: July 29, 2010

Please recognize our Customer No. 41552 as our correspondence address.